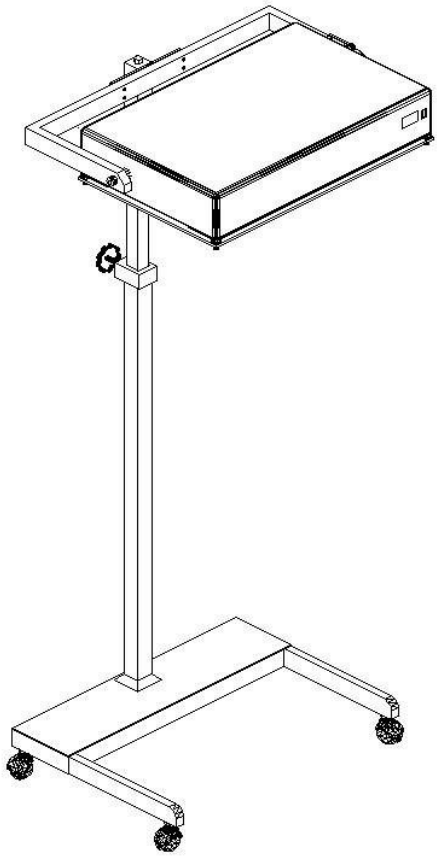
TLC 2H
INFANT PHOTOTHERAPY UNIT

Instruction for Use



TESENA

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TLC 2H Instruction for Use Rev 01

PT. Tesena Inovindo
Jl. Jusin 43 Susukan Ciracas
Jakarta Timur 13750
Indonesia

Telephone +62-21-8412414
Fax +62-21-87792140
Email: support@tesena.co.id
www.tesena.co.id

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1 Product Description

The Tesena TLC 2H is an overhead phototherapy unit with roll stand. The unit contains four fluorescent lamps emitting blue light with certain wavelength useful for jaundice therapy. The lamp's enclosure height can be adjusted vertically along the roll stand rod to have the effective distance to the patient. It can also be tilted from horizontal position to have the effective angle for radiation.

1.1. Intended Use

The TLC 2H Phototherapy unit is intended for the treatment of infant with hyperbilirubinemia (jaundice). The unit can be used for infants in a baby cot, bassinet, bed, incubator or under radiant warmer. The unit is equipped with castors to provide mobility.

1.2. Specifications TLC 2H

TLC 2H / 1H

Power Source	: AC 220VAC , 50Hz
Power Consumption	: 72W (4 lamps), 90W (5 lamps), 108W (6 lamps)
Lamps	: 4,5,6 blue light Fluorescent tubes 400-500 nm with electric ballast
Blue light Intensity	: 62µW / cm^2/ nm (4 Lamps at distance of 30 cm)
Tube life time	: 1500 hours
Hour meter	: 0-99999,9 hours
Height adjustment	: App 120 - 165 cm
Housing of lamps	: App 65W x 43H x 13D cm
Mobile stand dimension	: App 65W x 43D x 110 H cm, knock down
Weight	: App 11 kg
Castor	: 2 inches

1.3. Drawing and Components

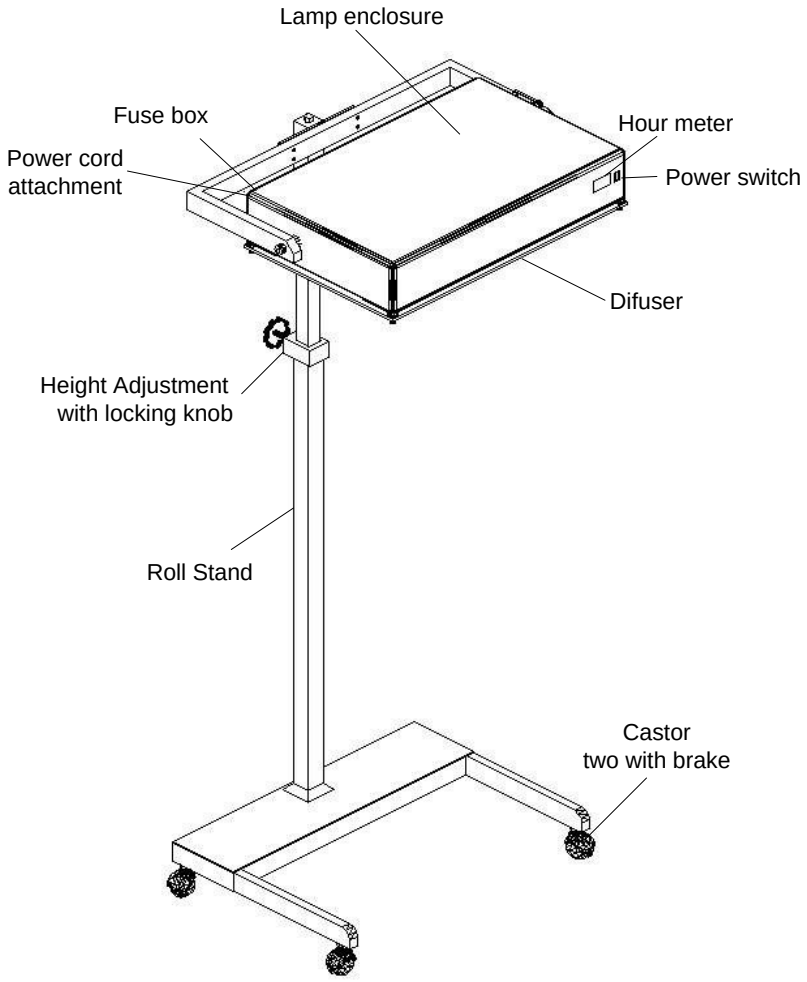

Figure 1: Main components of TLC 2H

Lamp enclosure: is the housing of the lamps, made of ABS material. It can be tilted in three different positions: horizontal, 45^{o}, and vertical (90^{o}).

Hour meter: shows the working time of the phototherapy unit, from 0 to 9999 hours. It helps user to control how long the therapy has been performed and the lifetime of lamps.

Height adjustment: the height of the roll stand is adjustable by free the locking knob

Diffuser: The diffuser provides more uniform illumination to the effective area of treatment.

2 Safety information

Please read all sections of this manual carefully before using the phototherapy unit. Follow all precautions to ensure the safety of the patient, user, and those near to the instrument.

⚠ Warning! This is a medical equipment. Only qualified personnel may operate this unit. People without authority may not operate this unit.

⚠ Warning! Incorrect use of this phototherapy unit or the use of parts that are not manufactured/supplied by PT.Tesena Inovindo can damage the unit and may cause hazardous situation to patient and/or user. Use only lamps which are recommended by the manufacturer.

⚠ Warning! Do not use the unit if the unit or its part is defect or suspicious as defect. Contact the manufacturer or distribution for technical support.

⚠ Warning! Operate this unit only in the treatment room. The light radiation may affect other people near to the equipment. The presence of other radiation sources may adversely affect the patient.

⚠ Warning! Do not use the unit in combination with other equipment. Incompatibility with other equipment could lead to incorrect function of the unit. Do not put things on the lamps discloser. This unit is not designed to endure load.

⚠ Warning! Do not look directly into the lamps. Always protect the baby's eyes with the protecting shields during treatment. The patient adjacent to the phototherapy unit may also need to be protected.

⚠ Warning! It is recommended to monitor the baby's skin temperature during treatment. Incorrect use of phototherapy unit may cause hazardous body temperatures.

⚠ Warning! Maintain the distance between lamps diffuser and the patient not closer that 30 cm.

⚠ Warning! If the baby lies in a thermotherapy device (incubator, radiant warmer or heated mattress), the use of phototherapy unit could impact the heat supply of those thermotherapy device.

⚠ Warning! Always switch off the power after finishing the therapy. Switch off the power and disconnect the power cord during cleaning and maintenance.

3 Assembly Instructions

The phototherapy unit is shipped in five separated components: head part (lamps compartment), foot part, outer and inner rods, and castors. It is recommended to utilize appropriate tolls to install the unit.
Assembly the unit with the following steps (see figure 2):

1. Unpack the shipping boxes carefully and check whether the component is complete.
2. Insert the inner rod into the outer rod. Tighten the locking part with the provided screw
3. Install castors to foot part. Press and rotate each castor counter-clockwise to fasten it to the foot part. Tighten with appropriate tools. Castors with break are installed in diagonal position
4. Install rods into foot part. Fix it with the provided screw
5. Install the head part to stand. Fix it with the provided screw

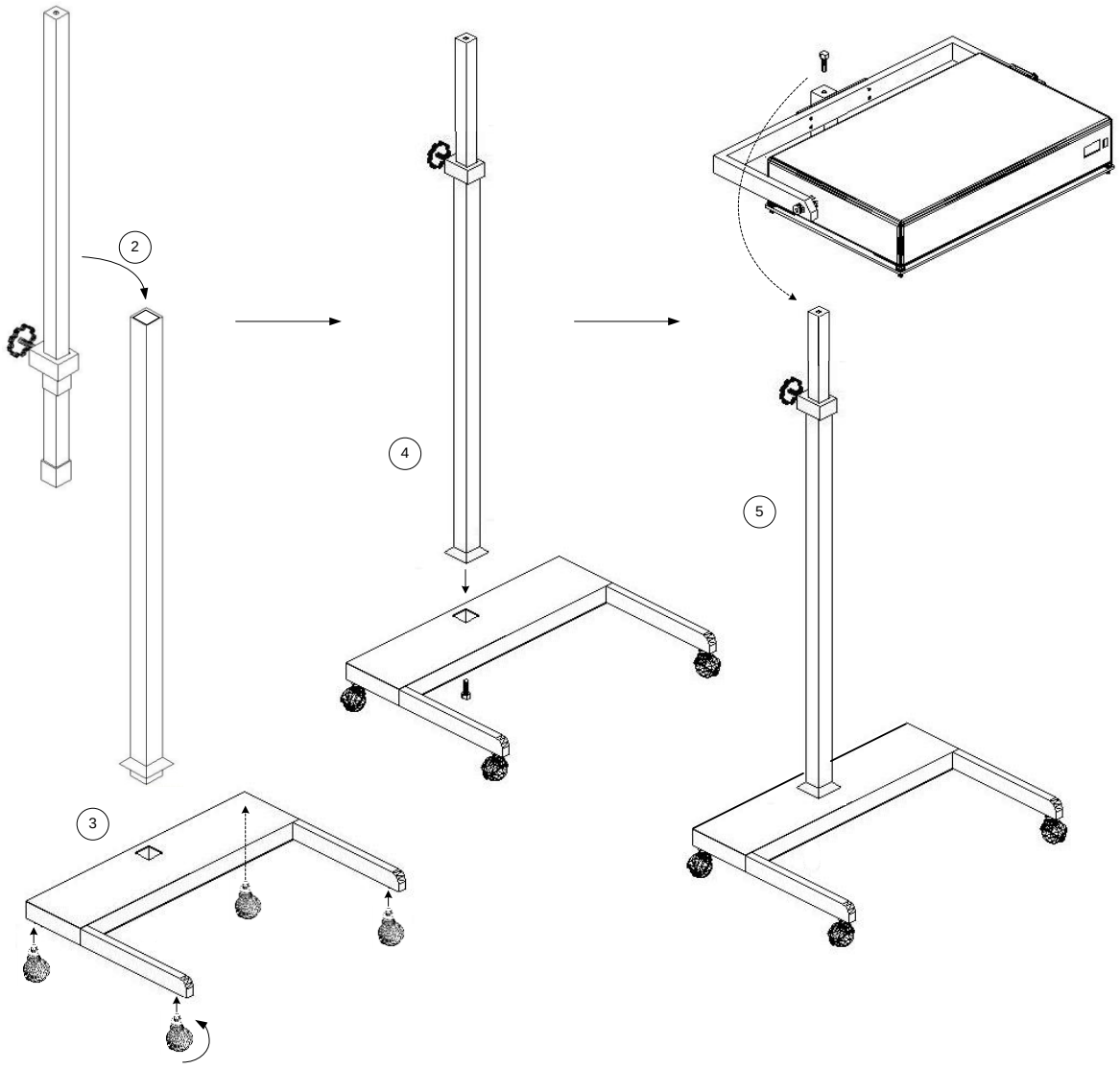

Figure 2: Assembly process

4 Operating Instructions

⚠ Warning! This is a medical equipment. Only qualified personnel may operate this unit. People without authority may not operate this unit.

⚠ Warning! Please read all the precautions and the operating instructions below before operating the unit.

⚠ Warning! The phototherapy unit could influence the body temperature of the patient. It is necessary to monitor the patient's temperature during treatment. Incorrect use of phototherapy unit may cause hazardous body temperatures.

Operating instructions:

1. Check the total irradiance. Check the total irradiance for bilirubin of the lamps before using the unit. This phototherapy unit provides an average irradiance of 405 $\mu W/cm^2$ at 40 cm distance.
2. Prepare the infant
   ⚠ Warning! Protect infant eyes with the eyes protecting shields appropriate for the phototherapy treatment.
   Infant may lie in a baby bassinet, baby cot, incubator or under infant radiant warmer. Free patient's skin from any cover to maximize the phototherapy effect.
3. Position the unit over infant. Adjust the height of the unit. The distance between patient and lamp's enclosure shall not closer than 30 cm.
4. Check the hour meter. Before use, note the working time shown by the hour meter to control the duration of the therapy.
5. Switch on power.
   ⚠ Warning! Never look directly into the phototherapy lamps.
   Make sure that the power indicator is ON, as well as the phototherapy lamps. The hour meter starts counting.
6. Monitor the patient. The patient shall be regularly monitored during treatment. Measure the patient's bilirubin level periodically. Turn off the unit during checking. Make sure that the baby's eyes are protected. When the therapy is finish, turn off the power.
   ⚠ Warning! always turn off the power switch before remove the power cord.

5 Troubleshooting Guide

⚠ Warning! always disconnect the power cord before opening the phototherapy unit for repair

Problem	Possible cause	Solution
The unit does not turn on. The power indicator is off	No power Defective fuse	Verify that the power cord in plugged in Check the fuse
Repeated defective fuse	Defective circuitry	Contact Tesena technical service or authorized distributor
Not all lamps are on	Loosely lamp starter Defective lamp	Verify that the lamps are installed appropriately Change the defective lamp
The unit will not move	Casters are locked	Unlock the casters

6 Maintenance

Cleaning

⚠ Warning! always disconnect the power cord before cleaning.
Clean the unit as well as the lamp enclosure with soft cloth dampened with water to remove dust and debris. Use commercial cleaner or hospital disinfectant if water alone is ineffective.

Checking the radiation source

The lifetime of the radiation source/blue light fluorescent lamp is limited. It is necessary to periodically check their total irradiance for bilirubin. The lamp shall be changed after a decrease of 25% of its total irradiance for bilirubin. All lamps have to be changed when the expected lifetime has been exceeded.

⚠ Warning! Use only lamps which are recommended by the manufacturer. The use of other lamps which are not approved by the manufacturer can influence the safety and effectivity of the phototherapy

⚠ Warning! only qualified personnel should perform this service.

7 Service

For product service and spare parts, please contact your distributor or directly contact us at:

PT. Tesena Inovindo
Jl. Jusin 43 Susukan Ciracas
Jakarta Timur 13750
Indonesia

Telephone +62-21-8412414
Fax +62-21-87792140
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